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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/174,937

Applicant(s)
CURTIS et al.

Examiner
Gabriele E. Bugaisky

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 17, 2000

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 4, 5, 8-12, and 27-41 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, 4, 5, 8-12, and 27-41 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other

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DETAILED ACTION

The amendment of 8/00 is acknowledged. Claims 1-2, 4-5, 8-12 and 27-39 remain pending and new claims 40-41 have been submitted.

Specification

The attempt to incorporate subject matter into this application (e.g. page 10, lines 19-24, page 11, lines 27-29) by reference to published journal articles remains improper because only issued or published U.S. applications may be properly be incorporated by reference.

The disclosure remains objected to because of the following informalities: all of the ATCC Accession Numbers (e.g., page 2, line 33, page 3, lines 27, 32 and 38, etc) have been left blank.. Applicants cite *in re Lundak* and state that Applicants reserve the right to amend the specification as originally filed to include the ATCC deposit information prior to issuance.

Appropriate correction is required.

The disclosure is also objected to because of the following informalities: incorporation of embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. (see, e.g., page 10, line 10 and line 15 and page 11, line 8, etc.)

Appropriate correction is required.

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The attempt to incorporate subject matter into this application by reference is improper because hyperlinks and/or other forms of browser-executable code are impermissible. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-5, 8-12 and 29-39 remain rejected and claims 40-41 are newly rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

It is stated that, based on sequence analysis and an apparent 66-70% identity of about 400-500 translated nucleotides to *mus* NIP2 and/or human Bcl2/E1B 19kD interacting protein 2, that the instant nucleic acids encode homologs of NIP2 and that they thus play some role in regulation of apoptosis. All function of the encoded proteins is by inference; no information is provided that the instant genes & constructs do indeed regulate apoptosis under any conditions. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving the claimed cDNA have asserted or identified specific and substantial utilities.

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The research contemplated by Applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the cDNA compounds such that another non-asserted utility would be well established for the compounds.

The Examiner's statements of the previous Action are incorporated here. Applicant's arguments filed 8/00 have been fully considered but they are not persuasive. It is stated that the utility of NIP 2 is known and that since the instant encoded proteins are homologues of that protein, they too have utility.

All function of the encoded proteins is by inference; no information is provided that the instant genes & constructs do indeed function like NIP2 under any conditions. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving the claimed cDNA have asserted or identified specific and substantial utilities. The research contemplated by Applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved

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does not define a "real world" context of use. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the cDNA compounds such that another non-asserted utility would be well established for the compounds. Because the art is cognizant that structural similarities in cloned genes or their encoded proteins do not *a priori* indicate functional similarities (see, e.g., Doerks *et al.*, Smith *et al.*, Brenner, and Bork *et al.*), further doubt is cast upon the utility and function of these disclosed sequences. Special attention is given to Brenner, (page 132, column 2, lines 28-33). in that sequence homology does not necessarily equate with function.

Applicants have obtained a cDNA putatively encoding proteins which are discussed in the specification as a NIP2 homolog, based upon sequence similarities. No specific properties of the claimed protein are discussed, nor are there any specific diseases discussed which can be treated by administration of the protein. Once the protein is obtained, the protein would be used in conducting research to functionally characterize the protein. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case proteins that are to be produced as final products of the encoding cDNAs have asserted or identified specific and substantial utilities. The research contemplated by Applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in

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which the protein is involved does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compounds such that another non-asserted utility would be well established for the compounds.

Even if one were to consider the specific embodiments having utility, there is insufficient teaching of what structural and functional properties are characteristic of NIP2 homologs to allow one to define a genus. The Examiner maintains that all function of the encoded proteins is by inference; no information is provided that the instant genes & constructs do indeed function in apoptosis like NIP2. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Evidence that the encoded proteins act as functional homologs of NIP2 could overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-5, 8-12 and 29-39 remain rejected and claims 40-41 are also newly rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, is withdrawn, based upon the amendment.

Claim Rejections - 35 USC § 102

The rejection of claims 38, 9 11, 12 and 39 under 35 U.S.C. 102(b) as being anticipated by Boyd *et al.* (ref. AI) is withdrawn, based upon the amendment.

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Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

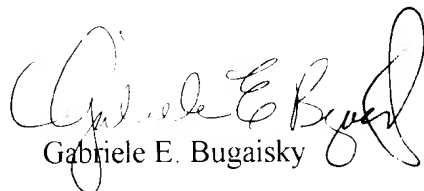
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 8:15 AM to 12:15 PM on Mondays and from 8:15 AM to 1:15 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

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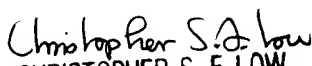
Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



Patent Examiner

July 16, 2001


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600